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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,180	04/07/2004	Peter M. Bonutti	2515 CIP DIV 2 CON B CON	7364
7590 Kimberly V. Perry U.S. Surgical A division of Tyco Healthcare Group LP 150 Glover Avenue Norwalk, CT 06856			EXAMINER THALER, MICHAEL H	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 10/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/820,180

Applicant(s)

BONUTTI, PETER M.

Examiner

Michael Thaler

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17, 19-21 and 23-31 is/are pending in the application.
- 4a) Of the above claim(s) 26-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17, 19-21 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Art Unit: 3731

Newly submitted claims 26-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 26-31 are drawn to the species of figures 29-34 which is patentably distinct from the species of figure 35 (originally claimed in claims 12-22).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 26-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-17, 19-21 and 23-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no basis in the

Art Unit: 3731

original disclosure for the limitation (in claim 12, line 4, for example) that the elongate tubular member is rigid, noting page 9, lines 3-6 of the specification and noting that the phrase "while a cannula is more rigid" on page 7, line 9 of the specification appears to refer to prior art cannulas. There is no basis in the original disclosure for the limitation in claim 23 that a retractor having a shaft and an expandable member is positioned in the elongate tubular member shown in figure 35.

Claims 12-17, 19-21 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are confusing and inaccurate since the elongate tubular member is flexible rather than rigid as set forth in the specification.

Claims 12-17 and 23-25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Taylor (3,952,742). Taylor discloses a device for providing a working passage comprising tubular member 12, bore 12a, the tubular member being rigid (when the tubular member 12 is rigidified by inserting the needle therein as described in col. 3, line 23 and col. 4, lines 2-5) and two wall segments 22, 24 longitudinally spaced apart (col. 2, lines 54-58). Alternatively, it would have been obvious that the Taylor

Art Unit: 3731

device for provides a working passage (claim 12) and is an access device (claim 19) due to the presence of bore 12a. As to claim 15, each wall segment is substantially flush with an exterior surface of the tubular member when uninflated since the amount the wall segment extends radially outward from the exterior surface of the tubular member when uninflated is very small as seen by the solid lines denoting members 22 and 24 in figure 1. As to claim 23, Taylor discloses a shaft (the main portion of needle 14) and expandable member (distal end 14a) which is inherently expandable (as broadly claimed) since pressing the diametrically opposite sides of the needle together to deform it would expand it laterally in a direction normal to the direction that the pressing force is applied. As to claims 24-25, as best understood, although the Taylor tubular member 12 is generally flexible, it has some rigidity.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (3,952,742) in view of Stevens (4,022,216). Assuming *arguendo* that the uninflated balloons 22, 24 of Taylor are not substantially flush with an exterior surface of the tubular member, Stevens teaches that it is desirable to make the uninflated balloon 32 of a balloon catheter lie flat within a recess to be flush with the outer surface of the support member (figure 4) and thus apparently

Art Unit: 3731

make insertion of the device into the body less traumatic. It would have been obvious to make balloons 22, 24 of Taylor also lie flat within a recess so that it too would have this advantage.

Applicant's arguments filed August 6, 2007 have been fully considered but they are not persuasive for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

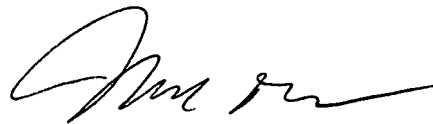
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael

Art Unit: 3731

Thaler whose telephone number is (571) 272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

mht



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731